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As an AstraZeneca patent survives a tenth invalidation challenge in China, Jianhui Li of Wanhuida Intellectual Property considers the implications for generic drug makers and the pharmaceutical industry

On June 10 2025, the CNIPA issued Invalidation Decision No. 587641 (the Decision), affirming the validity of invention patent ZL200780024135.X (the Patent) owned by AstraZeneca AB. The Decision, which sheds light on the protection scope of 'Swiss-type claims' in drug crystal patents, could serve as a point of reference in formulating patent drafting and validity defence strategy in the pharmaceutical industry.

Background to the case

The Patent relates to a dapagliflozin crystal form titled "Crystalline solvates and complexes of (1S)-1,5-anhydro-L-C-(3-((phenyl)methyl)phenyl)-D-glucitol derivatives with amino acids as SGLT2 inhibitors for the treatment of diabetes". Dapagliflozin, which is a blockbuster product of AstraZeneca, is an SGLT2 inhibitor currently approved for the treatment of chronic kidney disease, heart failure, and type 2 diabetes.

Claim 1 of the Patent protects the dapagliflozin (S)-propylene glycol hydrate structure (the SC-3 Crystalline Structure). Claim 9, which is a Swiss-type claim, protects the use of said crystalline structure in the manufacturing of a medicament for treating diabetes, insulin resistance, hyperglycaemia, hyperinsulinaemia, elevated blood levels of fatty acids or glycerol, hyperlipidaemia, dyslipidaemia, obesity, or diabetic complications in mammals.

The petitioner initiated an invalidation action challenging the validity of the Patent, contending that since claim 9 did not specify whether the finished pharmaceutical product contains the SC-3 Crystalline Structure described in claim 1, claim 9 encompasses two technical solutions:

Solution A – the medicament contains the SC-3 Crystalline Structure; and
Solution B – the medicament is prepared using the SC-3 Crystalline Structure as raw material, but the active ingredient in the finished pharmaceutical product is a dapagliflozin compound, which does not contain the SC-3 Crystalline Structure.

The patentee rebutted that, according to the description, claim 9 covers both the technical solution of the drug containing the SC-3 Crystalline Structure as the active ingredient and that of the drug containing a dapagliflozin compound as the active ingredient.

The petitioner challenged the Patent on multiple fronts, citing issues such as amendments extending beyond the original scope of disclosure, unclear specification, insufficient disclosure, and lack of inventive step, all targeting Solution B; i.e., the solution that does not include the SC-3 Crystalline Structure in the "medicament".

Therefore, the core dispute in this case centred on whether Solution B fell within the scope of protection of claim 9. That is, whether the protection scope of claim 9 included a scenario where the dapagliflozin SC-3 Crystalline Structure is used as a starting material for preparation, but the final formulation no longer contains this crystalline form.

The CNIPA's findings

The CNIPA approached the matter from multiple dimensions:

The CNIPA stated that, in essence, the Swiss-type claim is introduced as a workaround to the limitation of Article 25 of the Chinese Patent Law, which excludes “methods for diagnosis or for treatment of diseases” from patentable subject matters. The CNIPA underscored that it is imperative that the scope of protection of the Swiss-type claim be strictly limited to the medical use of the substance per se, banning any extension or expansionary interpretation that may result in erroneously covering the use of that substance as a starting material in the preparation of any medicament usable for treating a relevant disease.
The CNIPA affirmed that the statements made by the patentee during the substantive examination and invalidation procedures attest that the patentee had already clarified through amendments that claim 9 intended to patent the medical use of the SC-3 Crystalline Structure product. Therefore, it would be arbitrary if the claim were to be interpreted literally and thus be equated to the generation of a medicament with a certain therapeutic use, by using SC-3 as a raw material and subjecting such to a certain preparation process, thereby broadening the protection scope. The amendment to claim 9 is a mere change of the drafting form.
The CNIPA summarised that, judging holistically from the content of the specification, the Patent’s true contribution lies in proposing that a specific crystalline structure be directly applied as the active ingredient. The Patent neither involves the pharmaceutical use of the dapagliflozin compound nor makes any disclosure related to further transforming the crystalline structure into the dapagliflozin compound and using such as the active pharmaceutical ingredient. Therefore, the protection scope should not be inappropriately broadened as per the patentee’s interpretation.
The CNIPA concluded that a restrictive interpretation of claim 9 aligns with the patentee’s actual technical contribution. It risks disrupting the balance between the public good and private patent rights, if the scope of protection of claim 9 were to be interpreted mechanically and solely based on the literal expression of the claim, without factoring in the historical origins of Swiss-type claims and the context of the patent document.

The collegiate panel – after taking into account the legislative intent, prosecution history, support in the specification, and balance of interests – limited the scope of claim 9 to Solution A (pharmaceutical use of the SC-3 Crystalline Structure), which negated the petitioner’s invalidity action for Solution B and maintained the validity of the Patent. This marks the tenth invalidation challenge that the Patent has survived in China.

The implications of the CNIPA’s decision

The Decision is of great significance to the dapagliflozin drug and the wider pharmaceutical patent industry.

For dapagliflozin, this hard-won victory means that its core crystal form patent has emerged unscathed from repeated invalidation challenges, which attests to its stability and may discourage generic drug makers from lodging other invalidation actions.

For the pharmaceutical industry, the Decision explicitly defines the protection boundary of Swiss-type claims, specifying that they only cover medical uses “with specific substances as active ingredients”, rather than their indirect use as raw materials. This provides important guidance for innovator pharmaceutical companies that in patent drafting, the essence outweighs the form of claims. This means the patentee should avoid claiming excessively broad protection scope, as such an approach would endanger the stability of the granted patent.

The Decision is also welcome for providing a clear legal basis for generic drug companies to challenge secondary claims of crystalline patents.